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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/718,754 | 11/22/2000 | Kathryn K. Lappegard | 1189 | 3443 |
| 27310 | 7590 | 07/28/2004 | EXAMINER | |
| PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131 | | | BAUM, STUART F | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/718,754 | Applicant(s) LAPPEGARD ET AL. | |
| | Examiner Stuart F. Baum | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,21,40,41,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 6, 21, 40-41, and 44-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on 7/2/2004 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/718,754 is acceptable and a RCE has been established. An action on the RCE follows.

2. Claims 1-2, 6, 21, 40-41, and 44-45 are pending and are examined in the present office action.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 6, 21, 40, and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated promoter comprising a nucleotide sequence natively associated with and that drives expression of DNA coding for maize Jip1 (jasmonate induced protein-1), a nucleotide sequence set forth in in SEQ ID NO:1 or a nucleotide sequence comprising a fragment of the nucleotide sequence set forth in SEQ ID NO:1, or an expression

cassette comprising said promoter. The Office interprets “a nucleotide sequence set forth in SEQ ID NO:1” to mean any nucleotide sequence set forth in SEQ ID NO:1 which encompasses for example, a sequence comprising 2 nucleotides from SEQ ID NO:1.

Applicants isolated a 1,241 base pair Jip1 promoter sequence from maize whose sequence is set forth in SEQ ID NO:1 (page 4, 3rd full paragraph).

Applicants do not describe any promoter fragments of SEQ ID NO:1 nor do Applicants identify essential regions of the promoter sequence natively associated with the Jip1 coding sequence. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of promoter fragments falling within the scope of the claimed genus of promoters that comprise a fragment of SEQ ID NO:1 and Applicants fail to describe a representative number of promoter sequences natively associated with a maize Jip1 coding region. Applicants only describe a single promoter,

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namely the 1,241 base pair maize Jip1 promoter of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of promoters. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the maize Jip1 promoter of SEQ ID NO:1, it remains unclear what features identify a maize Jip1 promoter. Since the genus of maize Jip1 promoter of SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Amending claim 6 to recite “the nucleotide sequence set forth in SEQ ID NO:1” will obviate this rejection for claim 6.

Applicants’ Arguments and Office’s Response in regards to Written Description

Applicant's arguments filed 7/2/2004 have been fully considered but they are not persuasive.

Applicants contend that functional cis-acting elements are disclosed in the specification and that cis elements responsible for seed preferred [expression] were well known in the art at the time of filing as cited in Ezcurra et al (1999, Plant Molecular Biology 40:699-709, listed in IDS) (page 6, 1st and 2nd full paragraphs).

The Office contends that Applicants only disclose the TATA and CAT boxes, which are sequences that many different promoters from many different types of genes possess and the TATA or CAT boxes are not specific to Applicants’ promoter. The cis elements disclosed by Ezcurra et al are required for ABA-responsiveness and Applicants have not disclosed that the

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1241 base pairs of SEQ ID NO:1 comprise the B-box of Ezcurra et al and that Applicants' promoter is only made up of the B-box of Ezcurra et al.

Applicant contends that the MPEP only requires that the application "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter" (page 6, 3rd full paragraph).

The Office contends that disclosing a TATA and CAT box is not a "reasonable disclosure" that fulfills the written description requirement for claims drawn to any nucleotide sequence natively associated with any coding sequence for any maize Jip1 or for any nucleotide sequence comprising a fragment of the nucleotide sequence set forth in SEQ ID NO:1.

Enablement

4. Claims 1-2, 6, 21, 40-41 and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior

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art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated promoter comprising a nucleotide sequence natively associated with and that drives expression of DNA coding for maize Jip1 (jasmonate induced protein-1), a nucleotide sequence comprising a fragment of the nucleotide sequence set forth in SEQ ID NO:1, or the nucleotide sequence set forth in SEQ ID NO:1; or an expression cassette comprising said promoter.

The specification provides guidance for using the Genome Walker Kit to isolated a 5' region of the Jasmonate Induced Protein1 (Jip1) gene promoter from the maize line V3-4 A63 which was used as a probe for isolating a clone from the BAC library made from Mo-17 genomic DNA. Applicants presumably subcloned the 1241 base pair Jip1 promoter sequence, whose sequence is set forth in SEQ ID NO:1 (page 4, 3rd paragraph) into a plasmid, making the construct Jip1::GUS::pin II (pages 18-22, Examples 1-3). Applicants disclose the expression pattern of the endogenous gene was analyzed using Northern analysis (page 30-31, Example 6).

Applicants have not shown that the isolated promoter sequence consisting of the 1241 base pairs set forth in SEQ ID NO:1 does in fact replicate the expression profile as disclosed from the Northern analysis (page 30-31, Example 6). In addition, Applicants have not disclosed why SEQ ID NO:1 is 1247 base pairs in length and the Jip1 promoter is disclosed as consisting of 1,241 base pairs (See page 4, line 22).

Applicants are invited to submit a declaration which provides evidence that the claimed sequence has promoter activity.

The claims are broadly drawn to a fragment of SEQ ID NO:1 however, the instant specification, fails to provide guidance for which base of SEQ ID NO:1 can be altered and still maintain proper spatial and temporal seed-preferred expression. The specification also fails to provide guidance for which base can be deleted and which regions of the sequence can tolerate additions, base-substitutions or recombinations and still function as the full length promoter.

The state-of-the-art teaches using pieces of a promoter that do not contain the full compliment of cis-acting elements, will not produce the expression profile as observed using the whole promoter. Kagaya et al (1995, Mol. Gen. Genet. 248 :668-674) teach the rice chloroplastic aldolase promoter contains two elements, one of which acts as a negative element while the other acts as a positive element that confers developmentally regulated mesophyll cell specific expression. Removal of either of these regions changes the normal expression pattern (page 670, left column). Kagaya et al also teach that the promoter contains an element that serves as a target for light induction (abstract).

Benfey et al (1990, Science 250:959-966) teach that the 35S CaMV promoter consists of domains that individually regulate spatial expression within plants. "The combination of each of the five B subdomains with domain A results in an expression pattern that differs from that of the individual subdomains or domain A" (page 961, left column, 2nd paragraph). In other words, deleting a required domain will jeopardize the proper spatial and temporal expression pattern. In addition, Benfey et al (1989, EMBO J, 8(8):2195-2202; page 2200, left column 2nd paragraph) teach that not only are the promoter domains important for specifying proper spatial and temporal expression but that when all domains were present, the quantity of expression increased.

In the absence of guidance on essential promoter elements associated with the 1241 base pair sequence of SEQ ID NO:1, undue trial and error experimentation would be required for one of ordinary skill in the art to generate the hundreds of thousands of promoter fragments encompassed by the claims which read on any fragment of SEQ ID NO:1, prepare expression vectors comprising the different fragments of the 1241 base pairs of SEQ ID NO:1, transform plant cells, regenerate plants, select plants that have been transformed, and assay the transformed plants for expression in the proper tissues during the correct developmental time period.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicants' Arguments and Office's Response in regards to Enablement

Applicants request the basis for the assertion that the Ezcurra et al reference is required to be incorporated into the specification at the time of filing (page 7, 1st paragraph).

The Office asserts that Applicant has the duty to disclose all relevant information as specified in 37 CFR 1.56. If Applicant is relying on information only disclosed in the Ezcurra et al reference to make and/or use Applicants' invention, then that information should be included in Applicants' specification.

Applicants contend that compliance with the enablement requirement does not turn on whether or not an example is disclosed (page 7, 3rd paragraph).

The Office contends that the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without

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an undue amount of experimentation (MPEP 2164.02). In the present application, undue experimentation would be required as stated above.

5. SEQ ID NO:1 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Stuart F. Baum", with a stylized flourish extending from the end.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
July 20, 2004